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No. 90-476

In The

Supreme Court of the United States

October Term, 1990

WYETH-AYERST LABORATORIES DIVISION
OF AMERICAN HOME PRODUCTS CORPORATION,

Petitioner,

v.

MICHELLE GRAHAM, an Infant under the age of 18 who sues by her Parents, Guardians and Next Friends, CHARLES GRAHAM AND TAMMY GRAHAM,

Respondent.

BRIEF IN OPPOSITION TO WRIT OF CERTIORARI

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SUMMARY OF ARGUMENT

Respondent respectfully submits that this case does not warrant the Court's extraordinary and discretionary consideration. The court below remanded the case for further proceedings which could render expenditure of this Court's valuable resources unnecessary. The issue presented is not sufficiently important to merit this Court's attention: (1) This Court has previously denied certiorari sought by a DPT manufacturer on the same issues now asserted by petitioner; (2) Congress has

enacted legislation to placate petitioner's concerns and protect DPT manufacturers.

Congress has expressly rejected preemption of state law claims which, like respondent's, arose prior to October 1, 1988. Petitioner's preemption argument depends upon an oversimplified and misstated version of complex, disputed facts. The decision below is in accord with the uniform body of decisional law in the lower courts and is plainly correct.

COUNTER-STATEMENT

In this diversity action, respondent Michelle Graham seeks compensation for extensive brain damage which has rendered her severely multi-handicapped, with gross mental retardation and substantial physical disabilities.

Petitioner misstates the nature of respondent's claims as well as the facts concerning availability of improved vaccines and government approval of safer designs. Respondent prevailed on *three* claims at trial. The jury found, as facts, that petitioner's DPT vaccine was (1) unreasonably dangerous as the result of its design; (2) unreasonably dangerous as a result of inadequate warnings; and (3) petitioner was negligent in *testing*, designing and/or warning. (Special interrogatories 3-5, Pet. App. 79a).

1. The Design-Defect Claim and Alternative Designs Available

In 1947, petitioner ("Wyeth") began marketing its whole cell DPT vaccine. This same product has been

produced and marketed by Wyeth without any substantive change for the last forty-plus years and is the product injected into Michelle Graham in 1980 (TR 1102). Alternative vaccine technologies have existed since at least 1937 (TR 462-27, 917, 943). Additionally, universally recognized methods of purification of the whole cell vaccine have been available for several decades.

By 1958, Eli Lilly & Co. had developed an acellular, soluble vaccine which Wyeth admits was "superior to all others on the market, including Wyeth's" (Plaintiff's trial exhibit, "PX", 66). The Lilly soluble vaccine, Tri-Solgen, showed significantly fewer adverse reactions to whole cell vaccine and no serious effects such as convulsions and brain damage (TR 943). Wyeth's president and other officers repeatedly admitted that "fairly convincing evidence" established that Lilly Tri-Solgen was "less reactive," a "prestige vaccine" far superior to Wyeth's whole cell vaccine (PX 128, 66, 258, DX 228, DX 161). Through the Lilly process, 90% of the endotoxin was eliminated (TR 390). Lilly Tri-Solgen was greatly preferred in the medical community as a safe product and **obtained a vaccine market share of 50%**. Tri-Solgen was expected to eventually occupy 70% of the vaccine market (TR 389-91; 942-43). However, Lilly ceased marketing Tri-Solgen in 1977 and sold the rights to Wyeth.

By the mid to late 1950's, both Wyeth and the scientific community recognized that the whole cell vaccine was avoidably unsafe and that an acellular vaccine was a "high priority" in order to reduce the vaccine's toxicity and consequent dangers to children (PX 39, 41, 26, 42, 35). The success of the Lilly acellular vaccine, as a safer alternative, was well-documented and admitted by executives

at Wyeth (PX 96, 36; TR 373-77). To compete with Lilly, Wyeth's Dr. Tint applied for patent of an acellular vaccine process in 1960 which became known as Project 77A (PX 19). The patent application admitted the necessity for reducing adverse reactions to the whole cell vaccine and proposed a proven effective toxoiding process by which a safer soluble vaccine could be produced (PX 19, 35, 36, 39, 41, 42; TR 380-88). Dr. Tint's proposal advised Wyeth there was a significant problem in the whole cell vaccine and Tint stated in 1957, "It is strange only that presentation of a soluble pertussis product has been so long delayed" (PX 35; TR 379). Tint's vaccine patent was issued in 1962 (TR 383).

The Tint vaccine was used by Wyeth in Quadrigen, a vaccine containing DPT and Salk polio vaccine (TR 384). Quadrigen was proposed to compete with the quadruple antigen vaccine on the market by Merck, Sharpe & Dohme. The Merck vaccine contained a safer, less reactive soluble pertussis component as of 1959-60 (PX 663; TR 3055). Oral polio vaccine was developed which rendered the Salk vaccine no longer financially competitive and Wyeth abandoned Quadrigen. When it did so, it also shelved the safer Tint pertussis vaccine. The Tint project died from lack of manpower, facilities and financial support. Other projects were viewed as having a "higher priority" (PX 49). Despite the fact that at least two perfected, safer, acellular vaccines **had reached the market** by 1960, Wyeth continued to lag behind, never deviating from its whole cell product first licensed in 1947 (TR 384-88; PX 49, 41).

Twelve years after abandoning the Tint vaccine, Wyeth again researched a safer acellular DPT vaccine. In

1973, Dr. Carole Long was assigned the task of researching an acellular pertussis vaccine on a part-time basis (TR 2943). In the space of only a few months, Dr. Long succeeded in developing an acellular extract. Within one year, Dr. Long and her supervisor Dr. Rubin recommended that Dr. Long's work be scaled up to determine its viability at a production level (PX 59B, 60A, 60B, 61A, 63). Using the same techniques available since the early 1950's and in use by Lilly, Dr. Long had developed a pertussis extract offering "considerable protection" by September of 1975 (TR 2944, 2947, 2981-82, 2984, 3001, 3005-3007, 3009-10; PX 63, 61A, 61).

Dr. Long's extracted antigen, which was very similar to the Japanese vaccine introduced in the late 1970's, **repeatedly passed federal potency and toxicity tests** (TR 3002; PX 60, 61A). Despite recommendations by Wyeth doctors that the Long extract was a potentially successful acellular vaccine with tenfold less endotoxin, Wyeth did nothing to further Dr. Long's work (TR 460, 464). Instead, Wyeth decided to go after a ready-made acellular vaccine product, the Lilly Tri-Solgen (PX 66).

In 1977, Wyeth entered negotiations with Lilly to obtain the rights and technology to make Tri-Solgen, its "prestige" acellular vaccine (PX 66). Ultimately, Wyeth purchased both the Tri-Solgen trademark name and the acellular process, including the Lilly bacterial strains for manufacturing the purified vaccine (TR 392). During these negotiations, Wyeth executives consistently acknowledged the superiority of the Lilly vaccine and the need for Wyeth to convert from the whole cell to the safer acellular vaccine in order to reduce the reports of adverse reactions in the field (PX 66, 67, 69, 49, 53, 128, 142).

Scientific investigators reported the Lilly Tri-Solgen to be **equally effective but less reactive** than the whole cell (PX 258, DX 228, PX 74, 72). Wyeth agreed there was "little doubt" that Tri-Solgen caused less systemic reactions such as fever, vomiting, anorexia, hypotonia, collapse, shock, seizures, central nervous system disorders, and anaphlaxis (PX 128, 149B, 149C; DX 161).

2. Petitioner's Conduct In Thwarting Approval of Safer Designs

Wyeth chose not to manufacturer and market the superior, safer, and effective Tri-Solgen vaccine. Instead, Wyeth substituted its own seed strains and growth mediums and altered the Lilly manufacturing process so as to reduce the enhanced cost of manufacturing the acellular vaccine (PX 67; TR 393-400). The cost to manufacture the vaccine was measured as only a few pennies (TR 398; 1089), and – although about five-times the cost of whole cell – even a ten-fold increase would have raised the cost of manufacture to only one or two dollars, a price any parent would spend to provide a child with a safer vaccine (TR 398, 1114-15).

The Lilly Tri-Solgen lay dormant at Wyeth for five years, from 1977 to 1982. During this time, American children, including Michelle Graham, had no choice but whole cell vaccine although a safer acellular vaccine was owned by Wyeth. Finally, Wyeth sought a license amendment to allow it to substitute its cheaper version of the Lilly vaccine for its whole cell pertussis component and yet still name the vaccine Tri-Solgen (PX 142, 80A). The FDA refused to authorize the vitiated version of Tri-

Solgen but strongly advised Wyeth that its new acellular vaccine could be licensed without the Tri-Solgen trademark if Wyeth complied with the usual FDA requirements, removed the endotoxin and toxoided the exotoxin with formaldehyde, the toxoiding method available since 1937 (PX 80A, 66, 109, 142, 67; TR 395-402). Wyeth declined to follow the FDA's recommendation.

Although the acellular vaccine could easily have been licensed and marketed using existing technology available to Wyeth, Wyeth shelved the Lilly vaccine just as it had abandoned efforts to market its own alternative acellular vaccine (TR 395, 400-402). Neither Tri-Solgen nor Wyeth's version of it were ever offered to American children by Wyeth.

The improvements suggested by the Bureau of Biologies (FDA) could easily have been achieved by Wyeth. Dr. Wainwright and other Wyeth executives held a pertussis vaccine meeting during which they emphasized "the urgency of developing a new pertussis vaccine in a relatively short period of time" (PX 80A). The group acknowledged that making the changes indicated by FDA to Wyeth's existing acellular vaccine was "the quickest and easiest approach" (*Id.*). Wyeth failed once again to follow through and called a halt to the project to await the marketing in the U.S. of a new acellular vaccine perfected by the Japanese in the late 1970's, rights to which Wyeth hoped to acquire (PX 80). Wyeth's application for licensure of its acellular "Lilly" vaccine still languishes, "pending" at the FDA awaiting action by Wyeth.

The Japanese successfully developed an acellular vaccine by 1978 and Japanese children were receiving it

by 1981 (TR 457-58; PX 101; TR 460). The Japanese vaccine was hailed by Wyeth as an advancement over Wyeth's whole cell vaccine that was unmatched by anything Wyeth was producing (PX 80). Wyeth acknowledged that the "costs of litigation will be much less, perhaps none, with acellular vaccine" based on the Japanese experience of only one doubtful claim for over 15 million doses of vaccine (PX 94). Wyeth signed an exclusive supply and manufacturing agreement in 1982 with the Japanese company, Takeda, for the first generation acellular vaccine in Japan (PX 101). However, Wyeth once again failed to push forward with a safer alternative and never pursued production of the Takeda vaccine (TR 436), even though Wyeth executives admitted "the Japanese [have] proved the efficacy of their vaccine in a way that is quite impossible for us to duplicate" (PX 80). Instead, Wyeth had concluded by 1983 that it was advantageous to wait for the second generation Japanese vaccine of Dr. Sato to become available as it was cheaper and more profitable to make, and estimated the Sato vaccine to be likely to be on the market about two years after the Takeda vaccine (PX 101). As of 1985, Wyeth had still not moved ahead on the Japanese acellular.

In 1985, Wyeth began selling its whole cell vaccine to Lederle Laboratories (TR 437; PX 94). Wyeth kept its option open to market the Japanese acellular vaccine. (*Id.*) That option was never exercised. To date, the only DPT vaccine ever manufactured by defendant Wyeth is the toxic whole cell vaccine administered to Michelle Graham in March of 1980.

3. Improvements Available for the Whole Cell Design

In addition to the safer vaccines available, even the whole cell vaccine could have been improved. Defendant Wyeth had the capability to toxoid the vaccine with formalin, a process available and effective for over forty years (see *supra*.) Wyeth never used this simple method of reducing toxicity. Failing that, Wyeth could have measured and indicated the level of endotoxin present in its whole cell vaccine. Wyeth vaccine, placed on the market in lots, was greatly variable in endotoxin levels, thus rendering some lots far more reactogenic, or toxic, than others (TR 198, 279, 295). The toxicity varies highly from batch to batch and lot to lot, thus making the whole cell vaccine unpredictably unsafe (TR 267-68, 279, 295, 1030-32, 1120, 198). The number of adverse reactions, both local and systemic, are correlated to the level of endotoxin in the vaccine; i.e., the higher the level of endotoxin, the greater the risk of injury, brain damage, or death (TR 1035).

4. Petitioner's Failure to Provide Information

The Center for Disease Control (CDC) developed criteria for determining "hot lots" – lots which cause an elevated number of adverse reactions in children (PX 105, 88M). This effort included an attempt to obtain distribution data from vaccine manufacturers, which would help identify potential hot lots and determine whether Wyeth lots had higher rates of reactions than other DPT manufacturers (PX 88G, 105). CDC information had linked Wyeth whole cell to an excessive number of reactions as compared to other manufacturers (PX 105, 88F, 88G, 88M;

TR 209-10). Obtaining distribution data is essential because no estimate of reaction rates per lot is possible without knowing where and how much of the lots have been distributed (TR 213-17). Wyeth declined to supply the requested information (PX 88G; TR 213-17).

In 1979, several deaths from SIDS (Sudden Infant Death Syndrome) were reported to the CDC from Tennessee which were associated with a single lot of Wyeth whole cell vaccine (Bierly Depo., p. 62). Following this event, Wyeth changed its distribution policy so that no one lot or large portion of it would be distributed to "a single state, county or city health department" (PX 103). The effect of this redistribution was that it decreased the likelihood of an excessive reaction rate to a particular lot being detected by those gathering hot lot information (TR 1844-45). Clusters of adverse reactions would no longer occur and authorities would not be alerted that there might be something wrong with a lot of vaccine (TR 805). Likewise, such a distribution policy increases the likelihood of reporting error as well as failure to report reactions (TR 345). This makes it even more essential that the agency collecting reaction rate data have access to distribution information from the manufacturer. Only with this information is the CDC capable of accurately identifying potential hot lots and taking action to prevent their distribution. The DPT shot received by Michelle Graham came from just such a "hot lot" (TR 490-93, 465, 470; PX 105, 617).

5. Petitioner's Failure to Test

Testing for endotoxin levels is imperative, given the propensity of Wyeth whole cell to fluctuate enormously

in toxicity, as well as its tendency to increase in toxicity after release from the manufacturer (TR 800-803; 1042, 490-93). There is a simple, easily available method of measuring endotoxin content of each lot or batch, the limulus test, or LAL (TR 875-76). The LAL test has long been available, and in fact had been used by Wyeth to measure endotoxin content in the laboratory in 1975-76 (TR 885-86; PX 131). Use of the LAL test would permit Wyeth to measure the level of endotoxin and label each vial as to its endotoxin quantity, thereby providing critical information to treating physicians which would permit them to choose low-toxicity doses of pertussis vaccine for their patients (TR 883, 906). Further, such endotoxin testing would enable both the company and the medical community to correlate the rate of reactions to the endotoxin level, thus providing a valuable control mechanism (TR 391, 905; PX 321). Such monitoring and reporting of endotoxin levels would be of great benefit in understanding the vaccine's known toxic effects and would permit the development of testing data so as to monitor and prevent adverse reactions in children (TR 905-907, 891, 838). The use of the LAL test to quantify endotoxin was recommended to manufacturers by Dr. Geier in 1978, long before his involvement in DPT litigation (PX 321).

6. Petitioner's Failure to Adequately Warn

Most physicians have no idea whatsoever that there is endotoxin in Wyeth pertussis vaccine and none have any idea as to the quantity of endotoxin present (TR 874). Virtually everything in medicine must be certified as "endotoxin-free" by law. This is not the case with DPT

vaccine, even though FDA regulations require (1) manufacturers to advise, on the package label, if DPT contains "known sensitizing substances"; and (2) all unnecessary pyrogens or toxins must be removed from drug and vaccine products. Both endotoxin and exotoxin are known sensitizing substances. Endotoxin is a pyrogenic toxin unnecessary to the vaccine (TR 304, 837-875). *See* 21 C.F.R. 600.3(r), 610.13, 610.61(l) and (m). Nevertheless, petitioner has never labeled any of its DPT vaccine to (1) indicate the presence of endotoxin and (2) quantify its amount (TR 907). These failures – to toxoid the whole cell, test for endotoxin content, and label the vaccine accordingly – rendered the vaccine unreasonably dangerous and created severe risks which were easily avoidable (TR 942-44, 1014, 1021, 21718, 371, 377, 426-30, 475, 801 807, 830; PX 35, 41, 88E).

7. Congressional Action

In 1986, Congress enacted the National Childhood Vaccine Injury Act, Pub. L. 99-660, 42 U.S.C. § 300aa-1 *et seq.* (West Supp. 1990). In that Act, Congress expressly declared that "State law shall apply to a civil action brought for damages for a vaccine-related injury or death" for injuries, such as Michelle Graham's, which resulted from vaccinations administered prior to October 1, 1988. Pet. App. 164a. Additionally, under the Act, compensation for vaccine-related claims is paid by the government, not by manufacturers. The vast majority of claims have gone under the Act.

REASONS FOR DENYING THE WRIT

I. WYETH'S PETITION IS PREMATURE.

The Court of Appeals below remanded the case for further proceedings. Pet. App. A at 42a. Respondent recognizes that this Court may grant certiorari to review interlocutory decisions, but here there is no extraordinary reason sufficient to justify the unusual procedure of granting certiorari when no final judgment has been rendered. Petitioner has admitted that "under the terms of the Tenth Circuit's remand" review by this Court may be unnecessary: "[P]etitioner may, of course, prevail on other grounds on the retrial." Pet. Brief, p. 18, n.30.

This Court has indicated that it will not expend time and resources reviewing interlocutory orders of the courts of appeals "unless it is necessary to prevent extraordinary inconvenience and embarrassment to the conduct of the cause." *American Construction Company v. Jacksonville T & K.W.R. Company*, 148 U.S. 372, 384 (1893). This Court has denied certiorari, finding the case was "not yet ripe for review by this Court," because a court of appeals had remanded the case for further proceedings. *Brotherhood of Locomotive Firemen and Enginemen v. Bangor & Aroostook R. Co.*, 389 U.S. 327, 328 (1967).

Supreme Court Rule 11 expresses a policy consideration applicable here. That rule, which deals with cases pending in a court of appeals before final judgment is entered, specifies that a petition for a writ of certiorari to review a pending case "will be granted only upon a showing that the case is of such imperative public importance as to justify deviation from normal appellate practice and to require immediate settlement in this court."

This case may be resolved on retrial in a manner which would avoid the need for the expenditure of the precious judicial resources of this Court, and the petition is therefore premature and the case is not ripe for review. There has been no showing sufficient to establish "extraordinary inconvenience and embarrassment" or to justify "deviation from normal appellate practice."

II. PETITIONER PRESENTS NO NOVEL ISSUE: THIS COURT PREVIOUSLY DENIED A WRIT SOUGHT BY A DPT MANUFACTURER ON THESE ISSUES.

This Court has refused to grant certiorari to a manufacturer of DPT vaccine which advanced arguments identical to those now asserted by petitioner. *American Cyanamid Company v. Abbot by Abbot*, 488 U.S. 908 (1988), Resp. App. 6. That DPT manufacturer, American Cyanamid, argued, as does petitioner here, that certiorari should be granted because of a perceived conflict with the Fifth Circuit decision, *Hurley v. Lederle Laboratories* (Resp. App. 3). American Cyanamid also unsuccessfully argued that state law claims would frustrate congressional objectives concerning public health policy, for the same reasons now asserted by petitioner (Compare Resp. App. 3 with Petition, pp. iii, iv). Like Wyeth, American Cyanamid argued that the whole cell vaccine was the only vaccine approved by the government (Resp. App. 3). Like Wyeth, American Cyanamid argued that the National Childhood Vaccine Injury Act of 1986, in which Congress expressly allowed state law claims, did "not alter the preemptive effect of prior federal legislation." *Id.* In addition to these unsuccessful arguments, American

Cyanamid advanced an argument not raised by Wyeth, regarding specifications for government purchases. These arguments were fully briefed and supplemented with a substantial appendix. This Court found the arguments insufficient to merit certiorari.

III. CONGRESS EXPRESSLY ADDRESSED THE PREEMPTION QUESTION AND PRESERVED STATE LAW CLAIMS WHICH AROSE BEFORE OCTOBER 1, 1988.

Respondent's claim arose in 1980. In 1986, Congress enacted the National Childhood Vaccine Injury Act, Pub. L. 99-660, 42 U.S.C. § 300aa-1 *et seq.* (West Supp. 1990) ("the 1986 Act"). In that Act, Congress expressly declared, unqualifiedly, that "State law shall apply to a civil action brought for damages for a vaccine-related injury or death" for injuries which resulted from vaccinations administered prior to October 1, 1988. 42 U.S.C. § 300aa-22(a), Pet. App. 164a.

Petitioner incorrectly suggests that Congress did not consider particular types of tort remedies when enacting this legislation (Petition, p. 28). In determining that "State law shall apply", Congress was fully aware that state common law generally authorized compensation for vaccine-related injuries based on defective design or warning, even when the FDA had approved the design or labeling at issue. A Department of Justice official testified to Congress that under existing law, states were free to impose liability on "a negligence basis of liability or a strict product basis of liability, or . . . a no-fault basis of liability" and that compliance with federal regulatory requirements was not a complete defense. National

Childhood Injury Act of 1985: Hearings on S.827 before Senate Committee on Labor and Human Resources, Part 1, 99th Cong., 1st Sess. 236 (1985).

The House Subcommittee responsible for the legislation was made aware by its own staff that strict liability for defective design was an established part of state court law:

> To recover damages under state law, a victim of a defective product must prove fault on the part of the manufacturer. Fault does not necessarily mean negligence. It generally is sufficient for a plaintiff to prove that his injury was caused by a defect that was present at the time it left the hands of the manufacturer. Such a defect may be in the manufacturer or in the design of the product.

Staff Report of the Subcom. on Health and the Environment of the House Comm. on Energy and Commerce, 99th Cong., 2d Sess., *Childhood Immunizations*, 93 (Comm. Print 99-LL).

At that time, DPT manufacturers made their plea for congressional protection from precisely these types of state tort claims. The president of Lederle Laboratories, a DPT manufacturer, testified that "the major issues that have come forth in the cases brought against us have been failure to warn . . . and also defective design . . . because it is contended that there were better vaccines available and that we failed to provide them, therefore we were – we should be held liable." Vaccine Injury Compensation: Hearings on HR 1780, HR 4777 and Vaccine Injury Compensation: Hearing on HR 1780, and HR 4777 and HR 5184 before the subcommittee on Health and

the Environment of the House Committee on Energy and Commerce, 99th Cong. 2d Sess. 244 (1986).

Thus, Congress was fully cognizant of the particular types of state tort claims. Congress knew full well that "state law" included strict liability causes of action alleging that vaccines which had been licensed by federal agencies were defectively designed. Congress determined, with that knowledge, that "state law shall apply" to tort actions arising out of vaccinations prior to October 1, 1988.

The Court of Appeals for the Fifth Circuit recognized:

> Any case for preemption is doomed by the National Childhood Vaccine Injury ["NCVI"] Act of 1986 . . . Although the NCVI Act was passed after this case was filed, it is relevant as proof that Congress intends no preemption of the state law liability of vaccine manufacturers. The NCVI Act clearly states that state law remedies apply to the manufacture and sale of vaccines and it even makes recovery easier for injured consumers.

Hurley v. Lederle Laboratories, 851 F.2d 1536, 1540 (5th Cir. 1988); Pet. App. 112a.

The Fourth Circuit correctly observed that neither the 1986 Act nor comprehensive federal regulation prior to the Act preempted state claims: "The 1986 Act is replete with two powerful assumptions: one, state tort and contract actions are available without preemption by earlier federal legislation and two, following the 1986 Act's effect state law actions remain available. The 1987 Act

expressly states these assumptions." *Abbot by Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1113 (4th Cir. 1988).

IV. CONGRESS HAS ADDRESSED AND ALLEVIATED THE POLICY CONCERNS ARGUED BY THE PETITIONING DRUG MANUFACTURER.

Petitioner's brief argues a "parade of horrors" would befall the nation because jury verdicts would ostensibly conflict with uniformity created by FDA regulation. Petitioner suggests that if the nation's citizens, as jurors, continue to scrutinize the conduct of DPT manufacturers, those manufacturers will cease production, shortages will develop, "national health policy" will be undermined, and nationwide epidemics will result. This simply ignores the 1986 legislation by which Congress substantially reduced the legal liability of DPT manufacturers through a variety of methods. Under the Act, compensation for the vast majority of vaccine-related claims is now paid by the government from a trust fund. Pet. App. 149a, 153a, 155a. Regarding civil actions, the Act greatly reduced the liability of manufacturers for side effects and claims regarding inadequate warnings, by creating strong presumptions in favor of manufacturers and raising the burden of proof to clear and convincing evidence. Pet. App. 164a. The Act specifies:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. § 300aa-22(b)(1); Pet. App. 164a.

Wyeth would find additional protection from this language. The petition argues, at page 28, that this is "explicitly pre-emptive language governing suits arising out of immunizations occurring after the October 1, 1988 effective date of the Act". If true, the policy interest favoring certiorari is greatly diminished. In any event, the case now before the Court deals only with the narrow concerns raised by old, pre-Act claims.

Even such vintage claims will often fall within the government funded scheme. Wyeth admits that the "Compensation Act" provides attractive remedies for immunizations occurring prior to October 1, 1988, "including compensation for full future medical care and other costs," and "multi-million dollar awards". Petition, p. 27, n.35.

Petitioner's argument is apparently that preemption exists because DPT manufacturers, and hence, national immunization policy, would be destroyed by the few claims remaining outside the scope of the Act. A similar preemption argument has been rejected as "clouded with speculation." *See Hillsborough County v. Automated Medical Laboratories*, 471 U.S. 707, 720, 721 (1985), *citing* the trial court therein.

Likewise, *Hurley* found Wyeth's argument speculative:

> [T]he ultimate effect on vaccination levels is too uncertain for a court to intrude in what is essentially a policy question. Moreover, it is not clear that the cost of compensating children injured by the vaccine would drive vaccine manufacturers from the business; the manufacturers may be able to raise prices and preserve their profit

> margins. . . . [T]he decision to preempt state law products liability would be a difficult one for a policy-maker and it is not appropriate for us to assume that decision has been made based on such inconclusive evidence.

Hurley, supra, 851 F.2d at 1540.

V. THE DECISION BELOW FOLLOWS WELL SETTLED LAW AND IS PLAINLY CORRECT.

The court of appeals below, agreeing with the district court, observed "that federal preemption does not prevent state tort law awards arising from improperly manufactured drugs or vaccines, even in situations where the drugs or vaccines have met the FDA's minimum standards for licensing." Pet. App. 11a, n.9; *Graham v. Wyeth Laboratories,* 906 F.2d 1399, 1405, n.9 (10th Cir. 1990).

The decisions of the courts below are in accord with the overwhelming majority of courts which have considered federal preemption of state law regarding vaccines. At least sixteen federal courts have found no preemption.[1] Several state courts, including two State Supreme

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[1] Opinions which have found no preemption, in addition to the courts below, include *Abbot v. American Cyanamid,* 844 F. 2d 1108 (4th Cir. 1988); *Hurley v. Lederle,* 863 F. 2d 1173 (5th Cir. 1988); *Foyle v. Lederle Laboratories,* 674 F. Supp. 530 (E.D.N.C. 1987); *Percival v. American Cyanamid Company,* No. CIV-85-2671-P (W.D.Okla. Nov. 25, 1987) [available on Westlaw, 1987 WL 46954]; *Scholl v. Lederle Laboratories,* 684 F. Supp. 246 (D.Ariz. 1987); *Morris v. Park, Davis and Company,* 667 F. Supp. 1332 (C.D.Cal. 1987); *Macgilliviray v. Lederle Laboratories,* 667 F. Supp. 743 (D.N.M. 1987); *Wack v. Lederle Laboratories,* 666 F. Supp. 123 (N.D. Ohio, 1987); *Patten v. Lederle Laboratories,* 665 F. Supp. 745 (D.Utah 1987); *Smith v. Wyeth Laboratories, Inc.,* CA-84-2002

(Continued on following page)

Courts have found no preemption.[2] Only two courts have found preemption and both have been reversed.[3] Thus, the decisions on preemption are well settled, consistent and uniform. Those decisions are also consistent with the analysis of this Court, which found no preemption of local ordinances concerning blood plasma, despite comprehensive federal regulation. *Hillsborough County, Florida v. Automated Medical Laboratories, Inc.*, 471 U.S. 707 (1985). A finding of preemption and rejection of this uniform body of law would inject confusion and chaos into the established preemption doctrine.

Petitioner's argument ignores well settled principles of that doctrine. Comprehensive federal regulation of prescription biological products does not immediately create grounds for preemption. By definition, any subject

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(S.D.W.Va. Aug. 21, 1986); *Milam v. Lederle Laboratories Division of American Cyanamid Company*, No. CA-4-85-92-K (N.D.Tex. Oct. 15, 1986); *Jeski v. Connaught Laboratories, Inc.*, No. A-84-CA-395 (W.D.Tex. Dec. 18, 1986); *Knudsen v. Connaught Laboratories*, No. 85-703-CIV-J-16 (M.D.Fla. July 31, 1987); and *Koehlar v. Wyeth Laboratories*, No. 85-284-C (S.D.Ind. Sept. 8, 1987).

[2] *Shackil v. Lederle Laboratories*, 561 A.2d 511 (N.J. 1989); *White v. Wyeth Laboratories, Inc.*, 533 N.E.2d 748 (Ohio 1988); *Shepherd v. Lederle Laboratories*, No. 85-20330 (Cr.Ct. Broward County, Fla., Fed.3, 1988); *Duncan v. Connaught Laboratories, Inc.*, No. 86-CVS888 (Sup. Ct. Columbus County, N.C., Mar. 24, 1988); *Reed v. Connaught Laboratories*, 1426 Civil of 1985, (Court of Common Pleas, Monroe Co., Pa., Dec. 3, 1987)

[3] *Abbot v. American Cyanamid Company*, No. 86-857-A (E.D.Va. March 9, 1987) *rev'd* 844 F.2d 1108 (4th Cir. 1988); *Hurley v. Lederle Laboratories*, 651 F. Supp. 993 (E.D. Tex. 1986) *rev'd* 851 F. 2d 1536 (5th Cir. 1988).

that merits congressional legislation is a subject of national concern. That does not mean that every federal statute ousts all related state law. *Hillsborough*, 471 U.S. at 719 (1985). Rather, this court looks for special features warranting preemption. *Id.* No such special features exist to warrant preemption when, as here, Congress has expressly intended that state law claims be permitted.

Several presumptions and canons of interpretation are set against Petitioner. Even when Congress does not expressly state its intent, there is a presumption against preemption. *Maryland v. Louisiana*, 451 U.S. 725, 726 (1981). There is an even stronger presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause. *Hillsborough*, 473 U.S. at 715. This Court has been more reluctant to infer preemption from the comprehensiveness of regulations than from the comprehensiveness of statutes. *Id.* at 717. When preemption by regulation is considered, this Court is reluctant to find preemption when the agency concerned has not manifested a very clear intent of preemption, since agencies normally address problems in a detailed matter. *Id.* at 718. The presumption against preemption is even greater against preemption of state remedies, like tort recoveries, when no federal remedy exists. *Silkwood v. Kerr-McGee Corporation*, 464 U.S. 238, 251 (1984). At the time of Michelle Graham's injury, no federal remedy existed (and the 1986 Act, which ultimately created a federal remedy, expressly preserved state law remedies). Thus, all of these presumptions work against the petitioner in the present case.

VI. THERE IS NO SIGNIFICANT CONFLICT BETWEEN THE JUDGMENT BELOW AND THE *HURLEY* OPINION.

Relying solely upon *Hurley v. Lederle Laboratories*, Pet. App. 105a, petitioner urges that certiorari be granted because of a perceived conflict. As noted, Congress, two courts of appeals, and fourteen district courts have concluded that state law claims against whole-cell DPT arising before October, 1988 are not preempted.

There is no significant conflict between the judgment below and *Hurley*, which found that "any case for preemption is doomed" by the 1986 Act. Pet. App. 1121a. *Hurley* also observed "there is virtually no indication in the relevant law that Congress or the FDA explicitly or implicitly" intended to preempt state law. *Id.* at 113a. The court therefore held "federal law does not preempt state products liability law governing vaccinations." *Id.* at 118a.

Petitioner notes that *Hurley*, while rejecting preemption generally, left open the possibility that a narrow preemption claim might be assertable against design defect claims if a particular set of facts could be shown:

> *We do not decide this question* since we do not have the benefit of a district court's reasoning on it. We wish to make clear, however, that our holding against general preemption does not necessarily exclude the *possibility* of such a specific preemption. [Pet. App. 117 A, n.4 emphasis added.]

The failure to decide the question and the mere acknowledgment of a possibility of a specific preemption does not create a conflict. The logic of *Hurley*, even if

valid, does not resolve Michelle Graham's design defect claim and a retrial is still in order. Similarly, the *Hurley* decision makes no reference whatsoever to the type of testing claim advanced by Michelle Graham. That negligence claim involved testing of the whole cell vaccine already on the market. Use of an available test would have permitted Wyeth to measure the level of endotoxin and label each vial accordingly, so that the treating physician could choose low toxicity doses for their patients. Thus, petitioner's interpretation of the *Hurley* preemption analysis is not dispositive of at least two of Michelle Graham's three claims.

Regarding the labeling claim, *Hurley* suggested specific preemption only if "the FDA has processed all the relevant and available information in arriving at the prescribed warning." Pet. App. 116a. Here, the FDA did not process all relevant information in arriving at a prescribed warning because Wyeth did not use the LAL test to measure and report the level of endotoxin in each vial, even though FDA regulations require manufacturers to advise on the package label if DPT contains "known sensitizing substances". Endotoxin and exotoxin are known sensitizing substances. Thus, *Hurley* resolves none of Michelle Graham's claims.

Additionally, the limited preemption suggested in *Hurley*, based on whether "the FDA processed all necessary and available data", does not stand up upon examination, because Congress focused expressly on the preemption issue in the 1986 Act and did not make this a basis for preemption. The expression of congressional intent forecloses judicial implication of such a basis for preemption. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238,

252-56 (1984); *Hillsborough*, 471 U.S. at 714, 715; *Abbot*, 844 F.2d at 1113, 1114.

VII. PETITIONER'S ARGUMENT RESTS ON UNFOUNDED FACTUAL THEORIES.

Petitioner's argument relies upon a "conflict preemption" analysis which asserts that state law leading to safer vaccines conflicts with the scheme of federal regulation because the FDA has not approved marketing of any alternative to the whole cell vaccine. Petitioner's theory of "conflict" preemption depends on a fact argument supported solely by citations to the brief by *amicus curiae*, citations to the effect that the whole cell vaccine is the only vaccine that has been "adequately demonstrated" to merit licensure by the federal government. The *amicus curiae* was not a party to the proceedings below. Fact arguments now advanced in its brief were not subject to cross-examination or discovery. Conclusions of the *amicus* brief are neither part of the factual record of this case nor consistent with findings by the jury, which implicitly found, in determining that Wyeth's design was defective, that other safer, effective designs could have been used. Petitioner is attempting to induce this Court to sit as a trier of disputed facts. Wyeth seeks review based on alleged facts found adversely to Wyeth in the court below or not presented below.

Petitioner's fact argument ignores reality. The Lilly vaccine, Tri-Solgen, was approved, marketed, and obtained a market share of 50%. It was shown to be equally effective while being greatly preferred in the

medical community as a safer product. The FDA determined as recently as December, 1985, that Tri-Solgen still meets FDA standards for marketing. Wyeth personnel admitted that "fairly convincing evidence" established Tri-Solgen as a superior vaccine to Wyeth's whole cell vaccine. In fact, Wyeth purchased that vaccine. Eventually, Wyeth sought a license amendment to substitute a cheaper version of Tri-Solgen. The FDA refused to authorize the vitiated version of Tri-Solgen but strongly advised Wyeth that its new acellular vaccine could be licensed without the Tri-Solgen trademark if Wyeth complied with the usual FDA requirements. Wyeth declined to follow the FDA's recommendations.

In addition to Lilly's Tri-Solgen and Wyeth's cheaper version, Wyeth's extracted antigen, developed by Dr. Long, repeatedly passed federal potency and toxicity tests. The quadruple antigen vaccine **on the market** by Merck, Sharpe & Dohme contained a safer, less reactive soluble pertussis component, as did Wyeth's Quadrigen, which used the Tint vaccine. Federal regulations allow a pertussis vaccine that is fractionated – a split cell or acellular vaccine. 21 CFR § 620.1. Nothing prevented the petitioner from producing a safer vaccine and applying to the FDA for approval of safer alternatives.

Petitioner's argument ignores improvements that could have been made in approved, marketed whole cell vaccines. Nothing prevented Wyeth from improving its vaccine by using the available method of formalin to reduce toxicity. It is only through petitioner's parsimonious marketing attitudes that a safer vaccine was not approved and made available to children. Petitioner's argument would be credible only if Wyeth had diligently

pursued agency approval of a safer product. Wyeth cannot rely upon its own lax attitude to claim that a lack of government approval bars safer alternatives.

In *Hillsborough*, this Court rejected a "conflict preemption" argument involving comprehensive federal regulations of blood plasma. This Court noted that comprehensive regulation by Congress and the FDA contemplated additional state and local requirements – just as Congress contemplated state law claims in the 1986 vaccine Act. This Court found the federal requirements "merely established minimum safety standards." 471 U.S. 722.

Every court of appeals that has addressed petitioner's contention has discounted it. The Fifth Circuit rejected the notion that "conflict preemption" arises "because the FDA has not approved marketing of any alternative":

> We cannot accept this assumption because the FDA is a passive agency: it considers whether to approve vaccine designs only if and when manufacturers come forward with a proposal. [citation omitted] Thus, the absence of FDA-approved alternatives to the whole cell vaccine does not indicate FDA disapproval of any such alternative. There is no basis for finding a federal interest in a particular form of pertussis vaccine.

Hurley, Pet. App. 111a, 112a

Likewise, the Fourth Circuit in *Abbot* refused to find that state law would frustrate the national public health policy, given Congressional action expressly authorizing state remedies: "The overall goal of the PHSA and FDCA

is the safety of drugs and biologic products. That goal is more enhanced than frustrated by state law." 844 F.2d at 1113.

The Tenth Circuit below found that FDA standards were minimum standards for licensing and noted that "the district court correctly analyzed the preemption issue." Pet. App. 11a, n.9. The district court could not "agree that state tort remedies 'conflict with' the regulatory scheme. . . . [T]o the contrary . . . by allowing a tort action such as this to proceed, the national goal of optimum vaccine safety is actually enhanced." Pet. App. 61a, 62a.

CONCLUSION

Congress has expressly indicated its intent to permit state claims which, as here, arose before October 1, 1988. The Petition for Writ of Certiorari should be denied.

Respectfully submitted,

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APPENDIX A

No. 88___

In The

Supreme Court of the United States

OCTOBER TERM, 1988

AMERICAN CYANAMID COMPANY,
Petitioner,

v.

TRACY ISABEL ABBOT,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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QUESTION PRESENTED

Does federal law preempt a state common law design defect claim with respect to the only type of pertussis (whooping cough) vaccine that the federal government (1) licenses as safe and effective for sale, (2) actively promotes for use, and (3) purchases in large quantities for public distribution, where the claim is that the manufacturer should have produced a different and allegedly safer type of vaccine which the federal government is presently unwilling to license as safe and effective and which therefore cannot be lawfully marketed?

RULE 28.1 STATEMENT

Petitioner American Cyanamid Company has no parent company. In light of the purposes of Supreme Court Rule 28.1, petitioner construes the terms "subsidiaries" and "affiliates" to mean those corporations whose shares are publicly traded and a majority of whose shares are owned by American Cyanamid Company. American Cyanamid Company owns a controlling interest in Applied Solar Energy Corporation, but otherwise has no subsidiaries or affiliates so defined.

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OCTOBER TERM, 1988

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No. 87-7254. MURPHY *v.* HEDRICK, WARDEN. C.A. 4th Cir. Certiorari denied. Reported below: 845 F.2d 83.

No. 87-7282. MACIOCE *v.* CALIFORNIA. Ct. App. Cal., 6th App. Dist. Certiorari denied. Reported below: 197 Cal. App. 3d 262, 242 Cal. Rptr. 771.

No. 88-121. BARNETTE ET AL. *v.* UNITED STATES C.A. 11th Cir. Certiorari denied. Reported below: 846 F.2d 753.

No. 88-146. MATOS *v.* LEFEVRE, SUPERINTENDENT, CLINTON CORRECTIONAL FACILITY. C.A. 2d Cir. Certiorari denied.

No. 88-158. PHOENIX CANADA OIL CO. LTD. *v.* TEXACO PETROLEUM CO. ET AL., C.A. 3d Cir. Certiorari denied. Reported below: 842 F.2d 1466.

No. 88-169. MORISON *v.* UNITED STATES. C.A. 4th Cir. Certiorari denied. Reported below: 844 F.2d 1057.

No. 88-173. LINQUIST *v.* BOWEN, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL. C.A. 8th Cir. Certiorari denied. Reported below: 839 F.2d 1321.

No. 88-205. CAMPBELL ET AL., *v.* UNITED STATES. C.A. 6th Cir. Certiorari denied. Reported below: 845 F.2d 1374.

No. 88-255. GARRETT *v.* GENERAL MOTORS CORP. C.A. 8th Cir. Certiorari denied. Reported below: 844 F.2d 559.

No. 88-313. HALLMARK CARDS, INC., ET AL. *v.* HARTFORD HOUSE LTD., DBA BLUE MOUNTAIN ARTS, ET AL. C.A. 10th Cir. Certiorari denied. Reported below: 846 F.2d 1268.

No. 88-329. BODNAR ET AL. *v.* SYNPOL, INC. C.A. 5th Cir. Certiorari denied. Reported below: 843 F.2d 190.

No. 88-330. AMERICAN CYANAMID CO. *v.* ABBOT, A MINOR, WHO SUES BY HER MOTHER AND NEXT FRIEND, ABBOT. C.A. 4th Cir. Certiorari denied. Reported below: 844 F.2d 1108.

No. 88-331. LANE ET AL. *v.* DAVENPORT ET AL., C.A. 7th Cir. Certiorari denied. Reported below: 844 F.2d 1310.

No. 88-332. REED *v.* MANNHALT. C.A. 9th Cir. Certiorari denied. Reported below: 847 F.2d 576.